REMARKS/ARGUMENTS

Status of the Claims

Claims 1-25 are pending. Of these, Claims 14-25 are withdrawn from consideration, Claims 1, 3-4, and 7-13 amended and Claim 2 canceled herein.

Objections to the Claims

Claim 4 is objected to on account of a perceived discrepancy between the formulas in Claims 1 and 4. Applicants respectfully note that the wavy lines at both ends of the formula for L, $\{\!\!-L^1-A-L^2-\}\!\!$, are commonly used notations denoting the rest of the compound to which the moiety is attached. To further eliminate any confusion, Applicants have also corrected the typographical error within the body of Claim 4, which now reads " L^1 is a bond or a linker moiety covalently joining G ~~S~~ to A." Although Applicants believe Claim 4 is a proper dependent claim, it has been rewritten as an independent claim pursuant to Examiner's recommendations. Withdrawal of the objection is respectfully requested.

Objections to the Specification

The disclosure is objected to on account of: **1)** an allegedly improper incorporation by reference to a hyperlink and/or browser-executable code; **2)** a misspelling of the word "acetylgalactosamine" on pg. 42, line 13; and **3)** the use of a double colon in the last line of pg. 27 of the specification.

In response thereto, Applicants submit the foregoing amendments to correct the typographical errors noted in paragraphs [0180] and [0117] and remove the embedded hyperlinks from paragraphs [0300] and [0321] of the specification.

Furthermore, the specification was objected to for failure to provide antecedent basis for the subject matter of Claim 11. An issue under 37 CFR 1.75(d)(1) arises where the meaning of a given term used in the claims is not apparent from the descriptive portion of the specification with clear disclosure as to its import. In the present instance, Examiner's intent appears more focused on seeing the content of Claim 11 reproduced in the specification than on satisfying the provisions of 37 CFR 1.75(d)(1). Rather than risk adding new matter by virtue of attempting to weave in the content of Claim 11 into the body of the specification, Applicants respectfully decline as the request has no basis in law and the claim is supported by the specification as originally filed. Withdrawal of these objections is therefore respectfully requested.

Rejections under 35 USC §112, 1st paragraph

Enablement

Claims 1-13 are rejected under 35 USC 112, first paragraph, for allegedly not describing the claimed subject matter in such a way as to enable one of skill in the art to practice the claimed invention commensurate in scope with the claims. Applicants respectfully traverse this rejection in view of the foregoing amendments and for the following reasons.

Test of Enablement

As the Examiner is aware, the test of enablement is whether one reasonably skilled in the art could make or use the invention as claimed from the disclosure in the patent coupled with information known in the art without undue experimentation. *United States v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1046 (1989). *See* also MPEP 2164.01. The policy served by the test is to ensure that, in return for the grant of exclusivity provided by a patent, the inventor has provided a disclosure which enables the public to make and use his invention after the expiration of the patent. *Grant v. Raymond*, 31 U.S. 218, 247 (1832). A patent need not disclose what is well known in the art. *In re Wands*, 858 F.2d at 735. Not every last detail is to be described, else patent specifications would turn into production specifications, which they were never intended to be. *In re Gay*, 309 F.2d at 774. Thus, omissions in the specification do not render a patent invalid under the enablement standard, unless the omissions cause one skilled in the art to perform undue experimentation in order to practice the invention. *Hormone Research Foundation v. Genentech, Inc.*, 708 F. Supp. 1096, 1107 (N.D. Cal. 1988), *aff'd in part, vacated in part, and remanded*, 904 F.2d 1558 (Fed. Cir. 1990).

Importantly, and the Applicants stress, "the enablement requirement is met if the description enables any mode of making and using the claimed invention" and not every mode. *Engel Industries, Inc. v. Lockformer Co.*, 946 F.2d 1528 (Fed. Cir. 1991). Enablement "is not precluded even if some experimentation is necessary, although the amount of experimentation needed must not be unduly extensive." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367 (Fed. Cir. 1987).

Enablement Standard as Applied to the Presently Claimed Invention

A proper enablement analysis necessarily depends on proper claim construction. *In re Fisher* 427 F.2d 833, 166 USPQ 18 (CCPA 1970). To the extent that this rejection is based on various undefined variables in Claims 4, 10, 11, 12, and 13, Examiner is referred to the foregoing claim amendments. The claims are amended herein for improved technical clarity as the rejection seems to have arisen from some

confusion over the scope of the claims. In the present case, the pending claims are directed to ***compounds*** having the formula: Ab—G—L—T, and NOT to methods of treating cancer as seemingly alleged. *See* pg. 4, ¶2 of the Office Action dated April 29th, 2008. This distinction is particularly important as composition claims should not be held to the standard demanded of method of treatment claims.

Examiner's remarks in the Office Action further reveal an underlying doubt in the asserted utility of the claimed composition. The issue of an invention's efficacy or ability to do what is claimed is more properly framed as a question of utility falling under 35 USC 101. In particular, see MPEP 2164.07 (I) A, which states that Office personnel should not impose a 35 U.S.C. 112, first paragraph, rejection grounded on a "lack of utility" basis unless a 35 U.S.C. 101 rejection is warranted, which it is not in the present case. "[O]nly after the examiner has provided evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince one of ordinary skill in the art of the invention's asserted utility." *See* MPEP 2164.07

As a premise for the present rejection, Examiner notes that "the specification does not disclose any *in vivo* working example" of a compound for treating cancer or any disease. *See* pg. 5, ¶1 of the Office Action dated April 29th, 2008. In a proper enablement analysis, "the lack of working examples or lack of evidence that the claimed invention works as described should never be the sole reason for rejecting the claimed invention on the grounds of lack of enablement." *See* MPEP 2164.02. In the same token, *in vivo* data is not prerequisite to a finding of enablement.

To comply with 35 USC 112, first paragraph, a disclosure is deemed to satisfy the enablement requirement provided it describes the invention in terms sufficient to inform those skilled in the relevant art how to both make and use the claimed invention. *See* MPEP 2164. The Examiner's remarks imply that one of ordinary skill in the art, armed with the specification, would be unable to make and use the compounds of the invention due to suspected difficulties with the formation of antibody conjugates. As the state of the art in antibody technology is more advanced than characterized in the Office Action, Applicants would gladly provide some references to serve as background should the Examiner so desire. In view of the disclosure provided, *e.g.* paragraphs [0095]-[0101] of the specification, and the state of the art, Applicants submit that the pending claims are properly enabled. Those of ordinary skill in the art, at the time of filing, would be familiar with methods for producing recombinant antibodies specific for a particular antigen and with or without a native glycosylation site. Withdrawal of this rejection is therefore respectfully requested.

Written Description

Claims 1-13 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Applicants respectfully traverse this rejection in view of the foregoing amendments and of the following arguments.

As with the enablement rejection, the premise of the present rejection appears to be the scope entailed by the antibody moiety of the claimed invention. Applicants respectfully submit that the claims clearly do not encompass an unlimited scope. As was noted in the Action, sufficient written description for a genus can be achieved by a representative number of species within a broad generic.

Armed with *In re Gostelli*, Examiner construed the case to signify that the disclosure of two chemical compounds within a subgenus can not sufficiently describe a subgenus. While that may have been true for *In re Gostelli*, which was directed to bicyclic thia-aza compounds containing beta-lactam ring unsubstituted in beta-position and having antibiotic properties, precedent dictates that there is no absolute threshold for meeting the written description requirement for generic claims to biological subject matter. Instead, the determination will depend on a variety of factors, *e.g.* the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue, and other considerations appropriate to the subject matter. Irregardless, the instant specification explicitly disclosed antibodies that can bind to, *e.g.* CD20, CD3, TNF receptor, CD4, CEA, EGF and HER-2 receptor. Given that "antibody" is an art-recognized term, the present disclosure, *inter alia* pg. 19 and 38, is sufficient to inform those skilled in the art that the applicant was in possession of the claimed composition, without having to recite *ad nauseum* every antibody known in the art. Applicants therefore respectfully submit that adequate written description for the claimed invention is present. Withdrawal of this rejection is therefore respectfully requested.

Rejections under 35 USC §112, 2nd paragraph

Claims 4 and 10-13 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which application regards as the invention.

With respect to Claim 4, there was a question over the import of the wavy lines in the formula for L and the seeming lack of antecedent basis for the recitation of an "**S**" moiety. Applicants have since corrected the typographical error underlying the occurrence of an "**S**" moiety in Claim 4, which now

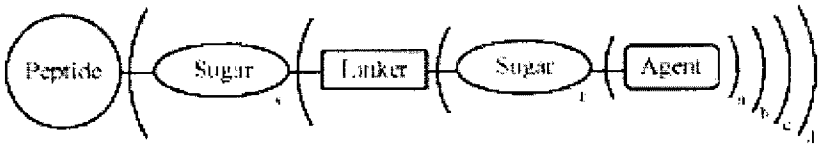
properly recites "L^1 is a bond or a linker moiety covalently joining G S to A." To reiterate, the wavy lines at both ends of the formula for L, $\{\!\!\{—L^1—A—L^2—\}\!\!\}$, are commonly used notations denoting the rest of the compound to which the moiety is attached. As such, withdrawal of this rejection is respectfully requested.

Furthermore, Applicants believe that the issues noted in Claims 10, 11, 12 and 13 are obviated by the foregoing claim amendments correcting various typographical errors found therein. Said amendments are supported by the specification as originally filed. Applicants wish to clarify, however, that the occurrence of "T" in Claim 12 is not a superscript. As consistent with the recitation in Claim 1, "T" is a toxin and need not be defined once more in Claim 12. Withdrawal of these rejection is therefore respectfully requested.

Rejection under 35 U.S.C. §102

Claim 1 is rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Leung *et al.* (1995) *J. Immunology* 154: 5919-5926. In view of the foregoing amendments incorporating the limitations of Claim 2 into Claim 1, Applicants respectfully submit that the pending claims possess novelty over Leung *et al.* Withdrawal of the rejection is therefore respectfully requested.

Claims 1-9 are rejected 35 U.S.C. §102(e) as allegedly being anticipated by U.S. Pat. No. 7,125,843. Patent No. '843 teaches conjugates having the following general structure:



> in which the symbols a, b, c, d and s represent a positive, non-zero integer; and t is either 0 or a positive integer. The "agent" is a therapeutic agent, a bioactive agent, a detectable label, water-soluble moiety or the like. The "agent" can be a peptide, e.g., enzyme, antibody, antigen, etc. The linker can be any of a wide array of linking groups, infra. Alternatively, the linker may be a single bond or a "zero order linker." The identity of the peptide is without limitation.

This is readily distinguishable from our compounds, which are characterized by the formula: Ab—G—L—T. As such, Applicants respectfully submit that the pending claims possess novelty over U.S. Patent No. '843. Withdrawal of the rejection is therefore respectfully requested.

Claims 4-6 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Kobayashi, *et al.*, (2000) Eur J. Nuclear Med 27(9):1334-1339. Since this rejection is premised on a misconstruction of Claim 4, Examiner is referred to Applicants' foregoing remarks under the sections entitled "Rejections under 35 USC 112, 2nd paragraph" and "Claim Objections." Furthermore, Kobayashi *et al.* does not teach a an antibody covalently joined to an antibody and a bond or space moiety. As such, Applicants respectfully submit that the pending claims possess novelty over Kobayashi *et al.* Withdrawal of the rejection is therefore respectfully requested.

Claims 1-4, 7 and 9 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 6,743,896. Applicants respectfully submit that this rejection is improper under the circumstances. Pursuant to 35 U.S.C. §102(b), a person is entitled to a patent unless "(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States." The instant application is however entitled to a priority date of September 2, 2003 while U.S. Patent No. 6,743,896 was issued on June 1, 2004, which postdates our priority date. Withdrawal of the rejection is therefore respectfully requested.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-442-1000.

Respectfully submitted,

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